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BS EN ISO 14644-8:2013



BSI Standards Publication

Cleanrooms and associated controlled environments

Part 8: Classification of air cleanliness by chemical concentration (ACC)

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This British Standard is the UK implementation of EN ISO 14644-8:2013. It is identical to ISO 14644-8:2013. It supersedes BS EN ISO 14644-8:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/30, Cleanroom technology.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Cleanrooms and associated controlled environments - Part 8:
Classification of air cleanliness by chemical concentration (ACC)
(ISO 14644-8:2013)

Salles propres et environnements maîtrisés apparentés -
Partie 8: Classification de la propreté chimique de l'air (ISO
14644-8:2013)

Reinräume und zugehörige Reinraumbereiche - Teil 8:
Klassifizierung der Luftreinheit anhand der
Chemikalienkonzentration (ACC) (ISO 14644-8:2013)

This European Standard was approved by CEN on 9 February 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 14644-8:2013) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14644-8:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14644-8:2013 has been approved by CEN as EN ISO 14644-8:2013 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14644-8 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

- *Part 1: Classification of air cleanliness*
- *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*
- *Part 3: Test methods*
- *Part 4: Design, construction and start-up*
- *Part 5: Operations*
- *Part 6: Vocabulary*
- *Part 7: Separative devices (clean air hoods, gloveboxes, isolators, mini-environments)*
- *Part 8: Classification of air cleanliness by chemical concentration (ACC)*
- *Part 9: Classification of surface cleanliness by particle concentration*
- *Part 10: Classification of surface cleanliness by chemical concentration*

This second edition cancels and replaces the first edition (ISO 14644-8:2006), which has been technically revised.

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Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food, healthcare, optics, instrumentation, vacuum technology, coatings, photovoltaics, displays, LEDs, coatings, automotive and surface analysis.

In some of these industries, the product or process can be sensitive to, or can be destroyed by, chemical contamination resulting from chemicals that are present due to external, process, or otherwise generated sources.

Within this part of ISO 14644, the presence of chemicals is expressed as air chemical contamination. Chemical contamination is a three-step event. The first step is *generation* due to external sources such as process leakage or construction material or personnel or material outgassing. The second step is *transport* as airborne chemical contamination. The third step is *sorption* on the sensitive surface, which can be quantified as a surface chemical contamination.

The generating materials and the surfaces where sorption takes place will have a large influence on the steps of generation and sorption in addition to the actual air contamination. Thus, for these two steps, not only the contaminants but also the involved bulk and surfaces need to be defined. In order to make a standard generally applicable to any type of cleanroom or associated controlled environment, air chemical cleanliness (ACC) has been chosen for the classification.

This part of ISO 14644 assigns ISO classification levels to be used to specify the level of ACC within a cleanroom and associated controlled environment, where the product or process is deemed to be at risk from air chemical contamination.

For classification purposes, this part of ISO 14644 is limited to a designated range of ACC and provides standard protocols for specifying such levels with regard to chemical compounds, methods of test and analysis, and time weighted factors.

Informative annexes are contained in this part of ISO 14644 covering:

- parameters for consideration: [Annex A](#);
- typical contaminating chemicals and substances: [Annex B](#);
- typical methods of measurement and analysis: [Annex C](#);
- considerations of specific requirements for separative devices: [Annex D](#).

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides ACC need to be considered in the design, specification, operation and control of cleanrooms and other controlled environments. These are covered in some detail in other parts of the International Standards prepared by ISO/TC 209, including ISO 14698 (all parts).^[4] In some circumstances, relevant regulatory agencies can impose supplementary policies or restrictions. In such situations, appropriate adaptations of this part of ISO 14644 can be required.

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Cleanrooms and associated controlled environments —

Part 8: Classification of air cleanliness by chemical concentration (ACC)

1 Scope

This part of ISO 14644 establishes the classification of air chemical cleanliness (ACC) in cleanrooms and associated controlled environments, in terms of airborne concentrations of specific chemical substances (individual, group or category) and provides a protocol to include test methods, analysis and time-weighted factors within the specification for classification.

This part of ISO 14644 currently considers only concentrations of air chemical contaminants between 10^0 and 10^{-12} g/m³ under cleanroom operational conditions.

This part of ISO 14644 is not relevant for application in those industries, processes or productions where the presence of airborne chemical substances is not considered a risk to the product or process.

It is not the intention of this part of ISO 14644 to describe the nature of air chemical contaminants.

This part of ISO 14644 does not give a classification of surface chemical contamination.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-6, *Cleanrooms and associated controlled environments — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-6 and the following apply.

3.1 General

3.1.1

chemical contamination

non-particulate substances that can have a deleterious effect on the product, process or equipment

3.1.2

air cleanliness by chemical concentration

ACC

level of air cleanliness by chemical concentration, expressed in terms of an ISO-ACC Class N, which represents the maximum allowable concentration of a given chemical species or a group of chemical species, expressed in grams per cubic metre

Note 1 to entry: This definition does not include macromolecules of biological origin, which are judged to be particles.

3.1.3

air chemical contamination

any substance in the air that can, by its chemical nature, adversely affect the product, process or equipment